

Message

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Subject: News Update: EPA's Latest Draft ETBE Risk Review Echoes Criticized 2009 Assessment (Inside EPA)

NEWS NCEA CAN USE

September 6, 2016

EPA's Latest Draft ETBE Risk Review Echoes Criticized 2009 Assessment

By Maria Hegstad, Inside EPA

Published September 2, 2016

Read the original article at: <http://insideepa.com/daily-news/epas-latest-draft-etbe-risk-review-echoes-criticized-2009-assessment>

EPA is floating a new draft assessment of the human health risks of the fuel oxygenate ethyl tertiary butyl ether (ETBE) seven years after release of an earlier draft, criticized by industry groups and others for relying on a contested study from an Italian laboratory for its cancer review – although the new analysis largely echoes the 2009 draft.

The agency released [the new draft assessment](#) Sept. 1, in advance of a public meeting scheduled for Oct. 26 in Arlington, VA. The agency is accepting written comments on the draft through Oct. 31. Industry groups are likely to attack the latest version as it mirrors conclusions on ETBE's cancer risks that they have said are wrong.

The new draft echoes its 2009 predecessor by concluding that ETBE presents "suggestive evidence of carcinogenic potential," though it uses as the basis for the conclusion a different study, one from the Japan Petroleum Energy Center industry research group, rather than the Italian Ramazzini Institute – the study faulted in the prior review.

EPA's 2009 draft reached the same conclusion regarding ETBE's carcinogenic potential, but declined to calculate a cancer risk estimate for ETBE due to limitations of the study on which it based its cancer assessment.

EPA in the new draft assessment goes further by calculating those risk estimates, or estimates of cancer potency, for ETBE. The agency explains that it "concluded that the main study was well conducted and quantitative analyses could be useful for providing a sense of the magnitude of potential carcinogenic risk."

EPA calculates an inhalation unit risk, or estimate of ETBE's cancer potency when inhaled, of 8×10^{-5} per milligram per cubic meter of air (mg/m^3). EPA then extrapolates from the same Japanese study to calculate an oral slope factor, or estimate of ETBE's cancer potency when ingested, of 9×10^{-4} per milligram per kilogram per day ($\text{mg}/\text{kg}\cdot\text{day}$).

EPA's decision will likely anger long-time industry critics of the assessment, who argued that EPA's 2009 conclusion overstated ETBE's carcinogenic potential. They questioned the 1999 study the conclusion relied on because it came from the Ramazzini Institute. Industry argued Ramazzini's unorthodox methodology overstated the risks of ETBE, methanol and other chemicals that its researchers studied. The Italian research lab traditionally preferred to conduct toxicology studies over the lab rat's natural lifespans, and not to use pathogen-free strains of rats or caging, as are used in most American studies, which generally conclude after two years at most. The American practices are intended to reduce confounding factors in study results, but a Ramazzini official argued in a 2010 interview with *Inside EPA* that his lab's approach better approximated human life.

Industry's Concerns

Following a 2010 review of some of Ramazzini's archived slides from its methanol study, pathologists with the National Toxicology Program (NTP) found discrepancies. That led EPA's former research chief, Paul Anastas, to review six IRIS completed and ongoing assessments because they referenced Ramazzini studies.

EPA eventually decided that it would not reference Ramazzini studies regarding leukemias and lymphomas. But EPA decided to utilize Ramazzini data regarding hard tumors in one of the six reviewed IRIS assessments, a completed assessment of vinyl chloride, because that data was found to be generally consistent with the NTP review.

More recently, when EPA announced that it was restarting the assessment in 2013, representatives of the American Petroleum Institute and the Japanese Petroleum Industry Technology and Research Institute pressed EPA to drop the ETBE assessment from its influential Integrated Risk Information System (IRIS) assessment program entirely.

They argued that ETBE has not been used in the United States since 1996, and the IRIS program should focus its limited resources on higher-priority environmental contaminants. But the chemical has been found at cleanup sites and in some groundwater sources.

Former IRIS chief Ken Olden in 2013 raised the possibility of shelving the assessment in response to industry's comments, but after discussing with colleagues in other EPA offices, concluded that there was a need for the assessment and it should go forward.

EPA briefly discusses the 1999 study by Ramazzini researcher Maltoni and colleagues in its latest draft – though it bases its ultimate conclusions on the newer Japanese studies' kidney tumor results.

EPA's latest discussion of the Ramazzini study mirrors industry concerns. "Interpretation of the study results reported by Maltoni et al. (1999) is complicated by the nonstandard histopathological diagnoses used and the greater than expected mortality in treated groups and controls compared with other laboratories," the draft states. "Low survival rates at 104 weeks (approximately 25%) in control groups confound these data because whether tumors in the control group were not observed due to premature death cannot be determined."

EPA noted that the NTP reviewers "found that the respiratory infections in the study animals confound interpretation of leukemia and lymphoma," and thus used the NTP reviewers' analyses "when considering carcinogenicity in place of the published Maltoni et al. (1999) study, and leukemia and lymphoma incidences from this study were not considered."

MTBE Assessment

Industry groups have long looked to the ETBE assessment as a bellwether to EPA's stalled IRIS assessment of the related fuel oxygenate methyl tertiary butyl ether (MTBE), which was more commonly used in the U.S.

Companies used MTBE for years to meet the mandate in the 1990 amendments to the Clean Air Act that set a minimum oxygen content for gasoline in order to cut air emissions.

EPA later discovered MTBE was a high-risk groundwater contaminant, and companies including Exxon Mobil have been embroiled in legal battles over cleanup costs. Most recently, the Supreme Court rejected in May Exxon Mobil's petition to overturn a New Hampshire decision that held the company liable for MTBE groundwater contamination, letting stand a \$236 million judgment against the oil company.

EPA's assessment of MTBE was never released following NTP's review of Ramazzini studies and the agency's decision not to use Ramazzini's MTBE data. The assessment is included in the agency's 2015 agenda for the IRIS program, listed in the third group of chemicals that the program will begin assessing over the next several years.

Among EPA's new ETBE findings that could offer hints on the MTBE study is a decision to loosen the proposed non-cancer inhalation risk estimate compared to the 2009 draft. This risk value, known as reference concentration (RfC), is defined as the greatest amount of a substance EPA estimates can be inhaled daily over a lifetime without experiencing a toxic effect. EPA, again using the newer Japanese study, calculates an RfC of $9 \text{ mg}/\text{m}^3$, compared with its 2009 proposed RfC of $0.0057 \text{ mg}/\text{m}^3$.

EPA selected additional Japanese data to calculate a proposed reference dose (RfD), analogous to the RfC but for exposure via ingestion. It proposes a first-time RfD for ETBE of $0.48 \text{ mg}/\text{kg}\cdot\text{day}$. The 2009 draft did not include a RfD because its technical panel concluded that there were too many uncertainties to do so. While the new draft includes a total uncertainty factor of 30, calculations excluded from the 2009 draft had a total uncertainty factor of 10,000.

Because of this high total uncertainty factor, EPA in the 2009 draft included the risk estimate only in an appendix, referring to it as an "oral minimal data value" and cautioning that it should only be used "in limited circumstances, for example, in screening level risk assessments or to rank relative risks."

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